Title page

Title: Cognitive Behavioural Therapy stabilises glycaemic control in adolescents with Type 1 Diabetes – outcomes from a randomised control trial

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Abstract

Aims: To compare the impact of cognitive behavioural therapy (CBT) with non-directive counselling (NDC) on glycaemic control and psychological well-being in adolescents with type 1 diabetes (T1DM).

Methods: Participants aged 11-16 year olds with T1DM (duration ≥1 year) from 4 UK based paediatric diabetes centres were randomised to receive either 6 weekly sessions of one-to-one CBT (n=43) or NDC (n=42), with 2 further sessions at 6 and 12 months. Follow-up continued for 12 months post intervention. Outcome measures included glycated haemoglobin A1c (HbA1c) and psychological scores.

Results: HbA1c levels were available in 33 patients in each group for analysis. Between group difference of the overall changes in HbA1c across the study period was statically significant (p=0.018). Geometric mean (range) HbA1c in the NDC group deteriorated from 68 (46-113) to 78 (48-128) mmol/mol, i.e. [8.4 (6.4 to 12.5) to 9.3 (6.5 to 13.9) %] (p=0.001), but was maintained in the CBT group from 72 (46-129) to 73(51-128) mmol/mol (p=0.51) i.e. [8.7 (6.4-14) to 8.9 (6.8-13.9)%]. More patients who have undergone CBT showed an improved or maintained HbA1c levels at 24 months (62.5 *vs* 35.5%, p=0.032). Patients offered CBT with depressive scores in the lowest tertile (least depressive symptoms) showed improvement in HbA1c over time from 70 (46-102) to 67(57-87) mmol/mol (p=0.041), i.e [8.6 (6.4-11.5) to 8.3 (7.4-10.1)%], but not in the NDC group. CBT showed borderline improvements in Children's Health Locus of Control (internal) scores over time compared with NDC (p=0.05). The Self-efficacy score showed significantly improvement in both CBT (p<0.001) and NDC (p=0.03) groups over time.

Conclusions: CBT demonstrated better maintenance of glycaemic control compared with NDC.

Introduction

Type 1 diabetes mellitus (T1DM) is one of the most common chronic health condition affecting children and adolescents. Long term prospective data have shown that intensive diabetes management in patients with T1DM is effective in reducing the development of long term complications and preventing early mortality (1)(2). However, optimal glycaemic control is challenging to achieve and highly dependent on the patient's adherence to lifelong daily multiple self-management tasks. Glycaemic control deteriorates in patients T1DM during adolescence (3,4) due to a combination of physiological, psychological and social factors (5). Adherence is a major challenge, particularly in patients with negative self-perceptions, who perceive little internal control over health and have an external attributional style for negative life events (6). Conversely, adolescents may be more likely to comply with interventions they believe to be effective (7), and whilst there is good evidence that parental involvement can improve adherence (8), this must be balanced against the need to achieve autonomy. Furthermore, psychiatric morbidity, ranging from major depressive, conduct, and generalised anxiety disorders (9), to milder symptomatology (10) has been described in T1DM and may impact on metabolic control (11–14).

In the U.K, psychological care is part of the multi-disciplinary care in all children and adolescents with diabetes under national guidelines (15). Individual randomised controlled trials in the past have suggested that psychological treatment may help to improve glycaemic control in children and adolescents with T1DM, but the overall evidence remained weak (16). In addition, there is a lack

of research comparing the efficacy of different types of psychological interventions offered to children and adolescents with T1DM.

Cognitive behavioural therapy (CBT) has been shown to be effective in a range of paediatric conditions compared with standard care (17), and reported as one of the most commonly used psychological intervention in children with T1DM (16). It is a structured time-limited, problem-orientated therapy based on the notion that a person's reaction to an event are largely determined by the meaning attached to the event rather than the event itself (18).

In this study, we hypothesised that CBT improves glycaemic control and psychological well-being by addressing cognitions leading to negative attitudes and behaviours associated with sub-optimal diabetes self-management. The primary aim of the study was to compare the impact of CBT and non-directive supportive counselling (NDC) on glycaemic control in adolescents diagnosed with T1DM. The secondary aim was to investigate changes in the psychological well-being in the participants treated with CBT vs NDC.

Methods

Study Design

This was a multi-centred, randomized controlled trial (NCT00360061) with 12-month post-intervention follow-up. Participants were randomised to CBT or NDC with stratification by gender and centre according to the minimization method (19) after a 3-month run-in period, with baseline dietetic education (3-day food diary and a home visit from a dietician) to compensate for potential variations in the

dietetic provision between participating centres. The participant's diabetes team was blinded as to the outcome of randomisation. Ethical approval for the study has been granted by the multi-centre research ethics committee (MREC 01/5/34) and participating hospitals in the South West of England.

Participants

Children and adolescents, aged 11-16 years, diagnosed with T1DM for over 12 months from 4 paediatric diabetes centres in South-West England, UK (Bristol Royal hospital for Children, Southmead Hospital, Gloucester General Hospital and the Royal Devon and Exeter Hospital) were approached by their diabetes team. Exclusion criteria included other serious chronic illnesses, special educational needs or residential care. As specified by the Ethical Committee, any participant identified as having a significant psychiatric or child safe guarding issue subsequent to recruitment, would be referred to the appropriate clinical team for further management and withdrawn from the study. Written informed consent from the carers and assent from the participant were obtained by the study coordinator. Standard multi-disciplinary diabetes management continued during the study.

Interventions

CBT was provided by a qualified CBT therapist and consisted of 6 one-to-one weekly sessions with single follow-up sessions at 6 and 12 months located according to the participant's choice, either in the primary care surgery or hospital out-patient department or participant's home. A specific CBT package was developed according to Beck's methodology (16) aiming to empower adolescents to develop and/or maintain appropriate attitudes to their diabetes, optimising diabetes self-care and

glycaemic control. Patients were given information sheets, homework assignments to complete at home that are discussed during the sessions. In summary, the programme addresses: 1) Developing and maintaining a therapeutic relationship. 2) Cognitive restructuring: identifying negative automatic thoughts, recognising associations between thoughts, feelings and behaviour and replacing with more balanced thoughts. 3) Problem solving (20), assertiveness training (21), relaxation. The therapist received weekly supervisions from a Consultant Clinical Psychologist (British Association of Behavioural and Cognitive Psychotherapies) who also reviewed a sample of audio-taped therapy sessions, to ensure faithfulness to the model.

NDC was provided by an experienced trained counsellor and was delivered to the same timetable as the CBT and was supervised by a Child and Adolescent Psychiatrist. Supportive counselling was client centred, non-directive, and provided time for the young person to express any issues/concerns.

Outcome measures

All participants had the following outcome measures:

1. Demographical and clinical data including baseline age, gender, age at diagnosis, number of years since diagnosis, age at recruitment, insulin dosage, diabetic complications, other medical conditions, family history of diabetes and Townsend deprivation index derived from participants' postcodes (22,23).

2. Glycaemic control assessed by capillary HbA1c samples obtained at recruitment (t=-3 months), end of run-in phase i.e. after the dietetic intervention and prior to the start of therapy (t=0 months), and 3, 9, 15 and 24 months calculated relative to the start of therapy. A single centralised DCCT

aligned laboratory by high performance liquid chromatography (COBAS® analyser, Roche Professional Diagnostics' Products, West Sussex, UK) was used.

3. Psychological measures by self-reported questionnaires at initiation (t=0 months) and 3 and 24 months of CBT or NDC including (see table 1 for reliability and validity):

a. Parcel-Meyer Children's Health Locus of Control (LOC) (24) assess the degree to which an individual believes their health is dependent on their own behaviour (internal), or is determined by others (powerful others), or to be a result of chance factors (chance). Subjects are asked to indicate "yes" or "not" to 20 statements about sources of health item and scored a point each. Higher scores represent higher locus of control in each subscale.

b. Well-being Questionnaire (WBQ) by Bradley et al (25) is a 22-item, multi-dimensional measure that assesses depression (6 items), anxiety (6 items), energy (4 items) and positive well-being (6 items). Each item is scored from a 4 point Likert scale from 0 to 3 indicating "not at all" to "all the time", and summed according to formulae. A higher score indicates more of the mood described by the subscale. A total well-being score is obtained by summing all scores of the subscales after reversing the anxiety and depressing scores.

c. Self-efficacy for Diabetes Scale by Grossman et al (26) evaluates adolescents perception of their ability and power in diabetes and related situation. Subjects are asked to rate their degree of confidence for 35 items with a 6-point Likert scale from 1 = "very sure I can't" to 6 ="very sure I can". Higher scores indicate greater diabetes self-efficacy.

d. Diabetes' Quality of Life for Youths (DQOL) (27) assess patients' perception of the impact of an intensified regime on the general satisfaction with life and on concerns over social and vocational issues related to diabetes. This is a questionnaire with 24, 11 and 17 statements scoring the patient's perceived disease impact, disease related worries and diabetes life satisfaction respectively. The items are scored on a 6 point Likert scale from 0= "never" to 5 = "all the time" or 0 = "very unsatisfied" to 5= "very satisfied". Higher scores indicate higher quality of life.

e. Diabetes Family Behaviour Scale (DFBS) (28): measures diabetes-specific family support. The scale can also be sub-analysed in 2 subscales to reflect guidance-control and warmth-caring. This is a 47 item questionnaire scoring on a 5 point Likert scale 1= "all the time" to 5= "never". A lower final score indicates greater family involvement.

Statistical analysis

Power calculation based on HbA1c mean [Standard Deviation (SD)] of 8.84(1.39)% [73.1 (15.3) mmol/mol] in 11-16 year olds (n=133) with diabetes diagnosed >1 year at the lead site indicated 31 subjects per group were required to give a 80% probability of detecting a 1% (11 mmol/mol) difference in mean HbA1c between two groups at 5% significance.

Demographical characteristics classed as continuous variables were compared by the 2-sided student t-test, while categorical data by the Chi-square or Fisher's exact tests as appropriate. HbA1c and psychology scores were analysed by repeated measures ANOVA using a compound symmetry model which uses all available results and accommodate subjects with missing data. The factors of

interest were the differences in longitudinal changes over time both between (as indicated by group x time interaction) and within groups. HbA1c results were positively skewed and logarithmically transformed prior to statistical analysis and reported in geometric means (ranges) in NGSP(%) and IFCC units (mmol/mol). Psychological scores were normally distributed and reported in mean and standard error (SE) HbA1c were compared at t=0, 3, 9, 15 and 24 months and psychology scores at t=0, 3 and 24 months where t=0 denoted the beginning of the intervention. Statistical significance was assumed at p-values of <0.05. Statistical software IBM SPSS for Windows version 23 (released 2015, Armonk, NY: IBM Corp) was used.

Results

Subjects and recruitment

The identification and recruitment process is summarised in figure 1. Out of 302 patients from all participating clinics, 87 eligible patients fulfilled the inclusion criteria and agreed to take part, but 2 withdrew and were excluded in the run-in phase. Having completed the run-in phase, 85 patients were randomised to CBT (n=43) and NDC (n=42). However, 19 participants disengaged from the study and never started the intervention. They were equally represented in the CBT (n=10/43) and NDC (n=9/42) groups with no differences compared with the remaining participants with respect to gender (Males: 47% *vs* M 44%) and family history of diabetes (25% vs 18%), but were slightly older mean age (SD) at diagnosis of diabetes: [9.2(3.6) *vs* 7.6(3.5) years] and recruitment to the study [14.3(1.5) *vs* 13.8(1.5)years]. The HbA1c at recruitment (t=-3 months) were significantly higher in the omitted cases than the

remainder [geometric mean (range) 77(55-134) *vs* 73(44-132) mmol/mol, p=0.043], [i.e. 9.2(7.2-14.4) vs 8.8(6.2-14.2)%].

The 'intention-to-treat' HbA1c analysis reported was based on 66 (CBT n=33; NDC n=33) participants who have taken part in the study (figure 1). During the study, 3 patients from the CBT group subsequently withdrew with non-attendance of intervention (n=1) and need for further psychological interventions (n=2). Two participants in the NDC group withdrew: one cited time constraints (n=1) and the other refused further sessions (n=1). In all 30 in the CBT and 31 in the NDC group completed the study.

Demographic data

There were no group differences in demographic characteristics, prevalence of diabetes complication, number of other medical conditions, family history of diabetes and presence of both parents at home (table 2). All patients in both groups of this study were on subcutaneous insulin injections. Dietetic home visits were completed within a mean (SD) of 3.8 (2.2) months.

Changes in Glycaemic control

HbA1c were positively skewed and log transformed before comparison. Within group comparison showed that mean log HbA1c increased significantly with time in the NDC (p=0.001), but remained unchanged in the CBT (p=0.51) group (table 3). Between group difference of the overall changes in HbA1c across the study period was statically significant (p=0.018). The number of participants who showed an improved or maintained HbA1c levels at 24 months was significantly greater in the CBT compared with the NDC group (62.5 *vs* 35.5%, p=0.032).

Psychological outcomes

Psychological scores of the 33 subjects in each group included in the analysis are shown in table 4. The Self-efficacy score showed significant improvement in both the CBT ($p<0.001$) and NDC ($p= 0.03$) groups over time, but there were no between group differences ($p=0.93$).

The internal LOC score showed a borderline increase over time in the CBT ($p=0.05$), no changes in the NDC group, and significant differences over time between the 2 groups ($p=0.041$). There were no within or between group differences in the other LOC subscales. There is a trend, however, towards lowering the LOC (powerful others) and LOC (chance) in the NDC group, but not the CBT group (the differences are not statistically significant).

There were no statistically significant between group differences in the WBQ total or sub-scores. However, there was a statistically significant reduction of WBQ (depression) scores in the NDC group ($p=0.019$) and a non-significant reduction in the WBQ (anxiety) scores in the NDC group. Sub-analysis of subjects with WBQ depression scores in the lowest tertile (least depressed) demonstrated significant reduction in HbA1c over time in the CBT group ($p=0.041$), no within group changes in the NDC group, and significant between group differences over time ($p=0.008$). (table 3)

Discussion

The outcomes of our study have shown that a short course of CBT over a 12-month period prevented deterioration of glycaemic control in adolescents with T1DM, whilst an increase in HbA1c overtime was observed in participant who underwent NDC mirroring the pattern observed in clinical practice and population based studies (3,4). Stabilisation of HbA1c is important as the Diabetes Control and Complication Trial (DCCT)(1)(2) identified that all improvements in HbA1c are beneficial, even in adolescence, in delaying the onset or slowing the progression of diabetic complications. The prevention of HbA1c deterioration in this study is a clinically significant result in itself, and further studies are warranted to investigate if an improvement following CBT may be associated with the increased length of intervention, follow up and /or sample size, or inclusion of patient psychological characteristics and symptoms.

Outcomes of the psychological assessments demonstrated improvements in some but not all areas over time in one or both groups. In particular, CBT showed an improvement in the Internal Locus of Control score over the study period compared with NDC. This might be because CBT works on identifying and changing potentially distorted negative thoughts and unhelpful behaviours to improve patients' feelings. An improvement in self-efficacy was seen in both CBT and NDC groups with no between group differences. Similar findings have been shown in adults with T1DM offered CBT compared with blood glucose awareness training (29). However, the increase in self-efficacy scores may merely be a reflection of improved self-confidence as the patients gain experiences in their diabetes self-management over time that is independent of the psychological therapy offered.

Our results showed an improvement in depression scores over time in the NDC group, but this may be due to the lower baseline score at the beginning of the intervention. The other reasons for the observed differences could be in the nature of the interventions. Namely, the NDC is by itself less-directive, less goal-oriented in itself more supportive and exerts less pressure and expectations on the patients. This could be also supported by the trend towards the reduction of WBQ anxiety scores observed in the NDC. However, the lack of group differences over time means NDC was no more effective than CBT in this aspect of well-being.

Interestingly, sub-analysis revealed an improvement in glycaemic control over time that was only shown in the subjects with depression scores in the lowest tertile (least depressive symptoms) in the CBT group. It is possible that adolescents with more depressive symptoms are less receptive to therapy within the short time frame and/or limited number of CBT sessions offered. A small study by McGrady et al have demonstrated improvements in depressive symptoms and diabetes management in adolescents with T1DM who have subclinical depressive symptoms after 12 sessions of CBT which was double the number of sessions offered compared with our study (30). In addition, evidence suggested that CBT may be ineffective in severe cases of depression (31). On the other hand, these patients with more depressive symptoms according to the results may be receptive to NDC to improve these symptoms. Therefore, formal baseline assessment for depressive moods should be undertaken to stratify the appropriate type and length of psychological interventions offered to patients.

In clinical practice, full formal courses of CBT or other psychological interventions are labour intensive with poor uptake in patients who are not motivated. However, it is possible to implement basic techniques of CBT in patients' during their routine care

by other health professional in the diabetes multidisciplinary team such as nurses who have undergone recognised training. Patients, who are least adherent or with more depressive symptoms, are also less likely to participate in interventions which require a lot of self-motivation as in the case of CBT. These patients might benefit from motivational or other techniques. Our data suggested that NDC could be considered over CBT as first line therapy in patients with more severe depressive symptoms.

However, there were no differences in a number of other psychological outcomes measured despite the better glycaemic outcomes in the CBT group in our study, which was consistent with previous findings (29)(32)(33). This indicates that the relationship between glycaemic control and psychological well-being is not straight forward. Further investigations into the influences of other factors, such as patient and carers' differences in learning style, degree of engagement, cognitive ability, and family functioning with therapy are needed.

The main strength of this study was its multi-centred design with the inclusion of patients from different paediatric diabetes centres of varied socio-economic backgrounds, so the results are more widely generalisable. However, there were some limitations in our study. Only 41% of the eligible patients approached agreed to participate in this study. Time constraints were an issue for many, while others did not feel the need for professional psychological interventions. The difficulties inherent in engaging an adolescent population in psychological interventions is not unique to our study. Despite this, the intention-to-treat HbA1c analysis has reached the expected numbers as per power calculation. Although there were a small number of drop-outs and missing data during the intervention period, our statistical analysis has employed

models which taken into account any potential bias among the participants and missing data points.

In conclusion, a short course of CBT offered to children and adolescents newly diagnosed with T1DM prevented the deterioration in glycaemic control which is otherwise observed. Greater improvement in glycaemic control was demonstrated in those offered CBT who were less depressed at the start of therapy. Subjects who had CBT showed greater belief that health is controlled by their own will. Both CBT and NDC may improve the self-efficacy in diabetes management. Further research is needed to explore which treatment indications, including patient characteristics, are most likely to improve clinical and cost effectiveness of psychological interventions in children and young people with T1DM.

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Table 1: Reliability and Validity of psychological scores

Psychology Score	**Reliability**	**Validity**
Self-efficacy (26)	*Kuder-Richardson coefficient* 0.90	Against locus of control r=0.42, p<0.001 Against self-esteem r=0.41 p<0.001 Against average bloods glucose value r=0.27, p<0.05
Childhood Health Locus of control (24) Overall	*Kuder-Richardson coefficient* 0.753	Against "standard" (Nowicki-Strickland Children's locus of control) r=0.501 (p<0.004)
Well-being (25) Depression Anxiety Energy Positive Well-being Total	*Cronbach's alpha coefficient* 0.68 0.74 0.64 0.80	Against patient rated diabetes poorly controlled r=0.23 p<0.01 (depression), r=0.21, p<0.01 (anxiety), no correlation with HbA1c
Diabetes Quality of life measures (27) Satisfaction Impact Worries	*Cronbach's alpha coefficient* 0.85 0.83 0.82	Against predictor of self-rated health status r= 0.42, p<0.01 r=-0.45, p<0.001 r=-0.45, p<0.001
Diabetes Family Behaviour Scale (28) Total Guidance-control Warmth-caring	*Cronbach's alpha coefficient* 0.86 0.81 0.79	Against HbA1c r=-0.12, p<0.03 r=-0.17, p<0.002 r=-0.06, p<0.29

Table 2: Demographic and clinical characteristics of the Cognitive Behavioural Therapy (CBT) and Non-directive Counselling (NDC) Groups

	CBT	NDC	p
N	**43**	**42**	
Gender: Male	44%	45%	0.92
Age at diagnosis of diabetes Median (range) years	8.4 (1.5-14.1)	8.2 (1.6-14.4)	0.92
Age at recruitment Median (range) years	13.2 (11.4-17.0)	14.1 (11.7-16.6)	0.10
Duration of diabetes at recruitment Median (range) years	4.6 (1.2 - 14.5)	5.7 (1.6 - 12.9)	0.56
Insulin dose per kg Mean (SD)	1.26 (0.39)	1.25 (0.39); n=40)	0.84
Diabetes Complications:			
Background retinopathy	1 (n=41)	2 (n=37)	0.60
Other	0 (n=41)	0 (n=37)	0.95
Other medical conditions (e.g. asthma, hayfever, eczema, hypothyroidism)	12	12	0.95
Parent or sibling with diabetes	6 (n=41)	10	0.29
Sibling in the study	3	3	>0.99
Both natural parents in participant's home	25 (n=38)	25 (n=40)	0.76
Townsend Deprivation Score* Median(range)	-1.94 (-4.15 - 5.04)	-1.62(-3.74 - 4.71)	0.79

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Where data are missing, the number of cases analysed are stated in parentheses.

Table 3: Summary statistics of the HbA1c values (in % and mmol/mol) for the CBT and NDC groups, at 0, 3, 9, 15 and 24 months.

		Between group differences						**Within group differences**
Intervention	**total n**	**Comparison**	**Baseline**	**3 months**	**9 months**	**15 months**	**24 months**	**ANOVA**
CBT	**33**	Geometric mean (range)	8.7 (6.4-14) 72 (46-130)	9.0 (6.8-12.8) 75 (51-116)	8.7 (6.0-11.8) 72 (42-105)	8.7 (6.4-12.2) 72(46-110)	8.9 (6.8-13.9) 74 (51-128)	0.51
NDC	**33**	Geometric mean (range)	8.4 (6.4-12.5) 68 (46-113)	8.6 (6.2-12.2) 70 (44-110)	8.9 (7.0-13.4) 74 (53-123)	9.0 (6.2-13.3) 75 (44-122)	9.4 (6.5-13.9) 79 (48-128)	**0.001**
		Intervention x time					**0.018**	
CBT *	**11**	Geometric mean (range)	8.6 (6.4-11.5) 70 (46-102)	9.2 (7.1-12.8) 77 (54-116)	8.2 (6.6-11.7) 66 (49-104)	8.0 (6.9-9.4) 64 (52-79)	8.3 (7.4-10.1) 67 (57-87)	**0.041**
NDC*	**11**	Geometric mean (range)	8.5 (7.0-12.4) 69 (53-112)	8.7 (7.1-12.2) 72 (54-110)	8.9 (7.6-13) 74 (60-119)	9.3 (7.0-10.7) 78 (53-93)	10.0 (6.5-14.2) 86 (48-132)	0.12
		Intervention x time					**0.008**	

* patients in the lower tertile of depression scores

Table 4: Outcomes of psychological interventions

			Between group differences				**Within group differences**
Score	**Intervention**	**total n**	**Comparison**	**Baselines**	**3 months**	**24 months**	**ANOVA**
Self-efficacy	CBT	33	Mean (SE)	158.5 (4.0)	166.2 (4.2)	172.4 (4.2)	**<0.001**
	NDC	33	Mean (SE)	157.9 (4.2)	165.6 (4.3)	170.0 (4.7)	**0.003**
			Intervention x time			0.92	
LOC	CBT	33	Mean (SE)	5.3 (0.15)	5.7 (0.17)	5.7 (0.17)	**0.05**
(internal)	NDC	33	Mean (SE)	5.6 (0.13)	5.5 (0.14)	5.3 (0.16)	0.42
			Intervention x time			**0.04**	
LOC	CBT	33	Mean (SE)	1.3 (0.26)	1.1 (0.29)	1.2 (0.29)	0.79
(powerful others)	NDC	33	Mean (SE)	1.6 (0.23)	1.4 (0.25)	1.0 (0.29)	0.20
			Intervention x time			0.52	
LOC	CBT	33	Mean (SE)	2.5 (0.22)	2.3 (0.24)	2.5 (0.24)	0.57
(chance)	NDC	33	Mean (SE)	2.4 (0.21)	2.3 (0.22)	1.9 (0.25)	0.12
			Intervention x time			0.21	
WBQ	CBT	33	Mean (SE)	5.5 (0.57)	4.9 (0.61)	5.4 (0.60)	0.41
(depression)	NDC	33	Mean (SE)	6.3 (0.48)	5.1 (0.49)	5.4 (0.57)	**0.019**
			Intervention x time			0.47	
WBQ	CBT	33	Mean (SE)	4.7 (0.55)	4.6 (0.59)	5.0 (0.58)	0.75
(anxiety)	NDC	33	Mean (SE)	5.9 (0.52)	5.0 (0.55)	4.8 (0.67)	0.21
			Intervention x time			0.30	
WBQ	CBT	33	Mean (SE)	7.5 (0.44)	7.6 (0.49)	6.7 (0.48)	0.17
(energy)	NDC	33	Mean (SE)	7.1 (0.34)	7.5 (0.36)	7.3 (0.44)	0.55
			Intervention x time			0.39	

WBQ	CBT	33	Mean (SE)	11.8 (0.61)	12.45 (0.65)	11.67 (0.64)	0.29
(positive)	NDC	33	Mean (SE)	11.24(0.57)	12.2 (0.59)	11.2 (0.69)	0.14
			Intervention x time			0.61	
WBQ	CBT	33	Mean (SE)	45.1 (1.9)	46.34 (2.0)	44.0 (2.0)	0.26
(total)	NDC	33	Mean (SE)	42.1 (1.6)	45.7 (1.7)	44.1 (2.0)	0.06
			Intervention x time			0.24	
DQOL	CBT	33	Mean (SE)	56.0 (2.3)	57.1 (2.5)	54.2 (2.4)	0.51
(disease impact)	NDC	33	Mean (SE)	55.0. (2.1)	57.6 (2.2)	56.2 (2.6)	0.55
			Intervention x time			0.73	
DQOL	CBT	33	Mean (SE)	20.3 (1.3)	21.5 (1.4)	20.5 (1.4)	0.65
(disease related	NDC	33	Mean (SE)	22.3 (1.7)	25.5 (1.8)	22.4 (2.2)	0.35
worries)			Intervention x time			0.65	
DQOL	CBT	33	Mean (SE)	64.2 (2.5)	63.8 (2.6)	64.5 (2.6)	0.93
(diabetes life	NDC	33	Mean (SE)	62.3 (2.4)	66.0 (2.5)	60.8 (3.0)	0.30
satisfaction)			Intervention x time			0.31	
DFBS	CBT	33	Mean (SE)	42.5 (2.0)	39.4 (2.3)	36.3 (2.2)	0.16
(guide & control)	NDC	33	Mean (SE)	38.3 (1.5)	35.8 (1.5)	36.1 (1.8)	0.23
			Intervention x time			0.54	
DFBS	CBT	33	Mean (SE)	49.3 (1.9)	47.1 (2.1)	46.4 (2.1)	0.50
(warmth & caring)	NDC	33	Mean (SE)	46.9 (1.2)	46.2 (1.3)	46.4 (1.5)	0.89
			Intervention x time			0.68	
DFBS	CBT	33	Mean (SE)	146.9 (5.2)	139.0 (5.9)	134.9 (5.7)	0.31
(total)	NDC	33	Mean (SE)	137.7 (3.1)	134.7 (3.3)	135.2 (3.8)	0.66
			Intervention x time			0.52	

Figure 1: Study Flowchart